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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,458	08/15/2003	Suman K. Chopra	IR 7419-00	2143

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COLGATE-PALMOLIVE COMPANY
909 RIVER ROAD
PISCATAWAY, NJ 08855

EXAMINER	
MOORE, MARGARET G	

ART UNIT	PAPER NUMBER
1712	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/642,458	CHOPRA ET AL.
	Examiner	Art Unit
	Margaret G. Moore	1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 to 14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 to 14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 8, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, reference to "the silicone resin" lacks antecedent basis.

In claim 9, reference to "the polydiorganosiloxane" lacks antecedent basis.

In claim 11, reference to "the adhesion enhancer" lacks antecedent basis.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 to 3, 6, 8 to 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/34221, herein '221 *and* anticipated by WO 01/01942, herein '942.

1) '221 teaches dental care compositions. See for instance page 7 which discloses a blend of a silicone resin, a silicone gum, a polydimethylsiloxane fluid and an oral care active compound. The combination of the silicone resin, gum and fluid results in a composition that creates a hydrophobic surface on the hard and soft tissues of the oral cavity, which remains substantive on surfaces of the oral cavity and can deliver the active compound. See column 4, lines 10 to 30.

The silicone resin/gum/fluid blend meets the requirements of the claimed hydrophobic pressure sensitive adhesive. First note that the silicone resin, gum and fluid adheres to the oral cavity surface and forms a hydrophobic surface. The fact that it ad-

heres to the surface upon application indicates that it is a pressure sensitive adhesive. Note too this particular composition meets the components found in claims 8 and 9. Thus the silicone adhesive in '221 meets the requirements of the adhesive in claim 1 as well as the limitations of claims 6, 8 and 9. Line 4 of page 27 teaches that the composition can be added as a single phase silicone system, meeting the requirement that the composition be anhydrous. Example 3 prepares an anhydrous composition, albeit with triclosan rather than a peroxide active agent.

Page 17 of '221 teaches various active agents for bleaching or removing stains from tooth surfaces. The third to the last line teaches that sodium percarbonate is a preferred compound. This meets the peroxide compound in claim 1 as well as the specific compound in claim 2. The top of page 18 teaches amounts that meet instant claim 3. Such amounts will correspond to a adhesive content meeting claim 13.

Thus, '221 teaches a silicone adhesive composition that contains, as a preferred active ingredient, sodium percarbonate. This composition is used as a tooth whitening composition; after it is applied to the surface of a tooth the peroxide compound is released. In this manner each requirement of claims 1 to 3, 6, 8, 9 and 13 is taught by '221.

Regarding claim 10, note that the term "adhesion enhancing agent" is extremely broad. Since each of the silicone fluid, gum or resin contribute to adhesion, each of these components meet this limitation.

2) '942 teaches a similar composition that contains silicone resin, siloxane fluid, a silicone gum and volatile carrier and an oral care substance. See the Summary on page 3. Particular attention is drawn to Tables 1 and 2 which show anhydrous compositions containing sodium percarbonate. This meets the component in claim 2 as well as the amounts in claims 3 and 13. While '942 does not specifically refer to the silicone resin/fluid/gum combination as a pressure sensitive adhesive, these components meet this requirement since, upon applying to the teeth (which requires exerting at least some pressure) the silicone resin/fluid adheres. See page 25, lines 3 to 20. It is this prolonged adhesive property that allows the oral care component to be released and to be

effective. In this manner the limitations of claims 1 to 3, 6 and 8 to 10 are met by '942 (note the rationale supra regarding the term "adhesion enhancing agent" as it applies to the resin, gum and fluid in '942 as well as the volatile carrier on page 8).

5. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by WO '942.

Note lines 1 and 2 and lines 20 to 25 on page 25 which teach steps (a) through (c). Lines 20 to 24 on page 5 teaches that multiple applications can be made, meeting step (d). This anticipates the method of claim 14.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over '221.

As noted supra, '221 teaches a nonaqueous tooth whitening composition that meets instant claim 1. Page 28 teaches applying the composition to the surface of the tooth by use of either an applicator or the finger. This meets the "painting" step (b) claimed. Page 28 also teaches that the product remains on the tooth for at least 2 hours a day, meeting step (c). While '221 does not specifically teach repeating steps (b) and (c) for multiple days, this would have been obvious. That is, one using the product of '221 and desiring the benefits of whitening or bleaching would have been motivated to repeat the steps that result in whitening or bleaching in an effort to enhance or intensify the results. As such claim 14 would have been obvious over the teachings of '221.

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over '221 as applied to claim 1 above, and further in view of Shiraeff.

'221 does not teach, as a bleaching agent, a PVP/H_2O_2 blend, although line 5 of the second full paragraph teaches that H_2O_2 is a suitable peroxide for use as an active ingredient.

Shiraeff teaches that "it is well known" that hydrogen peroxide is susceptible to deterioration or related degradation upon standing and storage. This can be overcome by stabilizing hydrogen peroxide with PVP in amounts meeting that in claim 5. See column 1, lines 25 to 50.

Thus one having ordinary skill in the art would have recognized that, when using the H_2O_2 in '221, long term stability may be adversely affected and would have been motivated by the teachings of Shiraeff to use the H_2O_2 in combination with a stabilizing amount of PVP, thereby rendering obvious the requirements of claim 4.

Regarding claim 5, note again that the top of page 18 in '221 teaches amounts of such active ingredients that fall within the claimed range. When the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

8. Claims 1 and 10 to 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cilento et al.

Cilento et al. teach an adhesive dressing containing an active ingredient. While the composition does not specifically teach that it is suitable for application to teeth or the "when applied topically to teeth..." requirement, these are future intended use limitations. The claimed composition is fully defined by the components therein (an orally acceptable anhydrous hydrophobic pressure sensitive adhesive and peroxide releasing compound). To meet the instant claims, it is the composition per se that must be met by Cilento et al.; the prior art need not teach the future intended use.

Cilento et al. teach an adhesive composition containing a hydrophobic pressure sensitive adhesive. See column 4, lines 10 and on. This adhesive is anhydrous. While applicants do not define the phrase orally acceptable in their specification, it appears that the polyisobutylene adhesive in Cilento et al. is orally acceptable since it is non toxic and is intended to be applied to skin[1]. Column 6, line 37, teaches the addition of benzoyl peroxide. This is a peroxide releasing compound. Cilento et al. thus teach a composition meeting each claimed component and as such anticipate instant claim 1.

Column 6, lines 42 to 50, teaches that the active ingredient is preferably found in a suspension in mineral oil thickened with a polyethylene and liquid petrolatum base.

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[1] Also supporting the Examiner's position that the polyisobutylene component in the adhesive of Cilento is considered to be orally acceptable, note WO 99/62472, which teaches adhesives used in an oral environment and include polyisobutylene (last paragraph of page 3).

This meets the requirements of claims 10 to 12. See line 45 on column 5 which teaches an upper amount of adhesive of 50 wt%. This anticipates the range in claim 13.

9. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/62472, herein '472.

'472 teaches a whitening strip that contains an adhesive having dispersed therein a whitening agent. The bottom of page 3 teaches various orally acceptable anhydrous hydrophobic adhesives and specifically teaches silicone. Such adhesives must be pressure sensitive since the strips are applied by contact (requiring pressure) to the teeth. Line 16 teaches that a preferred embodiment uses hydrogen peroxide as a whitening agent, meeting the claimed peroxide releasing compound. In this manner the composition of claims 1 and 6 are fully met by '472.

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over '472 as applied to claim 1 above, and further in view of WO '221.

'472 fails to teach sodium percarbonate as a whitening agent. However '221 teaches on the bottom of page 17 that hydrogen peroxide (the preferred whitening agent in '472) and carbamide peroxide and chlorine dioxide (also taught in '472) can be used as whitening equivalents of sodium percarbonate. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. In re Ruff 118 USPQ 343; In re Jezel 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. In re Font, 213 USPQ 532.

Thus one having ordinary skill in the art would have found the use of sodium percarbonate as a whitening agent in '472 in place of the functionally equivalent hydrogen peroxide, chlorine dioxide or carbamide peroxide to have been obvious. Adjusting the amount of agent in an effort to optimize whitening would have been within routine experimentation of the teachings in the prior art, thereby placing the limitations of claim 3 within routine experimentation and rendering them obvious.

11. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over '472 as applied to claim 1 above, and further in view of Shiraeff.

This rationale is consistent with that made in paragraph 6, supra. That is, it is known that hydrogen peroxide is unstable. Shiraeff teach that combining PVP with hydrogen peroxide results in a stable composition that can be used for bleaching. Thus one having ordinary skill in the art would have recognized that, when using H_2O_2 in '472, the long term stability of the adhesive may be adversely affected and would have been motivated by the teachings of Shiraeff to use the H_2O_2 in combination with a stabilizing amount of PVP, thereby rendering obvious the requirements of claim 4.

Regarding claim 5, note that the amount of hydrogen peroxide taught on line 16 of page 3 falls within this claimed range. When the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

12. Claims 7 to 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over '472 as applied to claim 1 above, and further in view of Pfister et al.

While '472 generally teaches silicone adhesives, it fails to teach specific types of adhesives. Pfister et al. teach silicone pressure sensitive adhesives that are compatible with drugs and excipients and are used in transdermal drug delivery and medical devices. Column 1 of Pfister et al. teaches that many silicone pressure sensitive adhesives lose their tack, adhesiveness and resistance to flow when combined with a drug. The adhesives therein overcome this problem and as such are improved silicone adhesives for use in medical applications including drugs or active ingredients. This adhesive comprises a silicone fluid and a silanol resin which can be condensed. See column 3, lines 10 to 45, which teaches the limitations of claims 7 to 9. The composition contains a "cohesive strengthening agent" (column 5, line 25) which meets the claimed adhesion enhancing agent of claim 10.

Thus one having ordinary skill in the art would have been motivated by the teaching of Pfister et al. to use the silicone pressure sensitive adhesive therein as the silicone

pressure sensitive adhesive in '472 in view of the benefits and properties associated therewith. As such the limitations of claims 7 to 10 are rendered obvious.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over '472.

'472 fails to specifically teach an amount of adhesive in the carrier layer on the whitening strip. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. As such adjusting the amount of adhesive in the whitening strip composition of '472 would have within routine experimentation and/or optimization of the adhesive properties of the strip in '472.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret G. Moore whose telephone number is 571-272-1090. The examiner can normally be reached on Monday to Wednesday and Friday, 10am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Margaret G. Moore
Primary Examiner
Art Unit 1712

mgm
11/22/04